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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/037,657 03/10/98 WILLSON

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GARDEN CITY NY 11530

EXAMINER

BRANNOCK, M

ART UNIT	PAPER NUMBER
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1646

17

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/037,657	Applicant(s) Hilton, DJ et al.
Examiner Michael Brannock, Ph.D.	Group Art Unit 1646

Responsive to communication(s) filed on Nov 20, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-29 and 31-48 is/are pending in the application

Of the above, claim(s) 1-19, 28, 29, and 31-34 is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 20-27 and 35-48 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-29 and 31-48 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

## **DETAILED ACTION**

### ***Status of Application: Claims and Amendments***

1. Claims 1-29, 31-48 are pending
2. Clams 20-27 and new claims 35-48 are currently under examination.
3. Applicant is notified that the amendments put forth in Paper 15, 11/30/00, have been entered in full.

### ***Response to Amendment***

#### **Withdrawn Objections/Rejections:**

4. All previous rejections of Claim 30 are withdrawn in view of Applicant's cancellation of the claim.
5. The objections to the specification, as set forth in items 3a, 3b, and 3c of Paper 13, 5/16/00, are withdrawn in view of the receipt of the certified copies of Australia PN 6135 and PN 7276, and in view of Applicant's amendments to the specification.
6. The rejection of claims 20-27 under 35 U.S.C. 112, first paragraph, for the reasons put forth in item 4 of Paper 12 is withdrawn in view of the finding that the claims lack a specific or otherwise substantial utility, as put forth in items 7a and 7b of Paper 12.

Art Unit: 1646

7. The rejection of claims 20-27 under 35 U.S.C. 112, second paragraph, for the reasons put forth in items 4b and 4c, of Paper 10, and reiterated in item 5a of Paper 12, is withdrawn in view of Applicant's amendments.

8. The rejection of claim 20 under 35 U.S.C. 102(b) as being anticipated by D'andrea, as set forth in item 5(a) of Paper 20 is withdrawn in view of Applicant's amendment to the claim to require a polypeptide of at least 90% similarity to that of SEQ ID NO: 1.

**Maintained Objections/Rejections:**

***Claim Rejections - 35 USC § 101***

9. Claims 20-27 and new claims 35-48 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, for the reasons put forth in item 7a of Paper 12.

Applicant argues that the polynucleotides disclosed in the specification (NR6) are required for embryonic viability in mice, and that therefore the polynucleotides and claimed polypeptides could be used in diagnostic assays for testing individuals in order to determine if they carrier a NR6(-) trait. This argument has been fully considered but not deemed persuasive because the instant specification has not asserted that aberrant expression of NR6 is the cause of

Art Unit: 1646

any disorder, human or mouse, outside of the laboratory. Therefore, the skilled artisan would not know how to use the polynucleotides to diagnosis any particular disorder.

Applicant argues that because the claimed polypeptides show homology to known members of the hemopoietin receptor family, then it is reasonable to assume that the claimed polypeptides are involved in the regulation of cell proliferation and differentiation. Thus, Applicant argues that the claimed receptor can be employed in those disorders associated with abnormal cell proliferation and differentiation. This argument has been fully considered but not deemed persuasive because the specification has not taught that which *particular* (if any) of the myriad disorders that are known to be associated with abnormal cell proliferation and differentiation could be treated and/or diagnosed with agonists or antagonist of the claimed polypeptide.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed polypeptides.

10. Claims 20-27 and new claims 35-48 are also rejected under 35 U.S.C. § 112 first paragraph, as put forth in item 7b of Paper 12. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the

Art Unit: 1646

reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Additionally, as set forth in item 3a of Paper 10, Applicant is notified that should Applicant establish a specific and substantial utility for the claimed polypeptides, Applicant has not provided sufficient guidance as to how to make and use the polypeptides which are not 100% identical to the polypeptides of SEQ ID NO: 13, 15, 17, 19, 25 or 29, but which still retain a desired property of the polypeptide of SEQ ID NO: 13, 15, 17, 19, 25 or 29.

On Page 7 of Paper 15, Applicant argues that one of skill in the art would know how to identify and to create or isolate amino acid substitution variants of SEQ ID NO: 13, 15, 17, 19, 25 or 29, e.g., specifically variants that are 90% identical to those of SEQ ID NO: 13, 15, 17, 19, 25 or 29. This argument has been fully considered but not deemed persuasive because the specification has not taught what these muteins would be used for. The issue is not that sequence variants could be created, but that the specification has not taught which variants, of the almost infinite number of variants that could be created, could be made that preserve and/or create any desired functional property of the polypeptide. Nor has the specification taught how to use any of the claimed polynucleotides that encode variants but which do not have any asserted functional properties. While it may be true that functional variants typically contain only conservative variation or variation in non-critical residues or non-critical regions, this teaching does not provide any information as to where these sites of conservative variation, non-critical residues, or non-critical regions could be - such information being necessary to enable the skilled

Art Unit: 1646

artisan to make and use the claimed invention without undue experimentation. Further, the specification failed to provide guidance as to what any particular functional property of the claimed polypeptide is; nor any particular functional difference between the polypeptide and sequence variants of the polypeptide. Thus, one of skill in the art would not know how to create a variant of a polypeptide having a particular function if that function was not known.

**New Rejections:**

***Claim Objections***

11. Claims 20, 22-27, 37, 39, and 43 are objected to because of the following informalities:  
The sequence identifiers in the claims require a space, e.g. SEQ ID NO:13 should be SEQ ID NO: 13. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

12. Claims 20-27, 35-41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20(i) and 35 require that amino acid sequences have a certain degree of "similarity", yet claims 20(ii) require that polynucleotides have a certain degree of sequence

Art Unit: 1646

identity. The use of both of these terms in the claims is confusing because it implies that there is a difference between the two, and such difference is not indicated. Upon further consideration of the issues raised in 4g of Paper 10, the examiner suggests to Applicant that the term "% identity" does not render the claims indefinite and therefore it is suggested that this term be used for both amino acid and nucleotide sequences.

As discussed in item 4d of Paper 10, claims 20, 39 and 41 recite the phrase "stringent conditions" without properly defining the conditions that Applicant considers to be "stringent". Claim 41 does not include the temperature of the wash conditions; the temperature of the wash will directly determine the bounds of the claim. It is suggested to Applicant that the format of claim 42 is adequate to define the metes and bounds of the claim, and that this format, applied to claims 20, 39, and 41, would obviate this part of the rejection.

Claim 39 contains the term [SEQ ID NO: 1]; the brackets are confusing because they imply that the sequence identifier is intended to be deleted through amendment. The use of parenthesis is suggested.

### *Conclusion*

13. No claims are allowable.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1646

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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January 4, 2001

*David Lanes  
Primary Examiner*